

## **REMARKS**

Claims 13 to 18 and 20 to 30 are pending in the application; claims 13 to 18, 20 to 27, and 29 to 30 are withdrawn.

### **Claim Rejections - 35 U.S.C. 112**

Claim 28 stands rejected under 35 U.S.C. 112, 1st paragraph, because the specification is only enabling for applying the gel to the skin or mucous membrane but not for generally applying the gel anywhere.

Claim 28 has been amended to specify in the body of the claim that the gel is applied to skin or mucous membrane, as suggested by examiner on page 5 of the office action dated 2/3/2010.

Claim 28 stands rejected under 35 U.S.C. 112, 2nd paragraph, because it is unclear what constitutes “calming” and what constitutes “normal skin”. Examiner states that neither one of the terms is a term of the art.

Applicant respectfully disagrees and submits herewith several publications in support of the term “calming” being well known and understood in the field of skin care and skin treatment/healing.

US 6,193,987 discloses a lubricating composition for hands and skin, In col. 2, lines 32-34, it is explained that the composition “will provide an organic calming and moisturizing composition to the skin...”. In col. 6, lines 29-31, it is explained that the “users found present invention superior for moisturizing and calming hands, throat and facial skin...”. In col. 6, lines 58-60, it is stated that: “It provides a calming and moisturing composition to the skin...”.

US 5,620,695 discloses a composition for treating minor skin irritations. According to the Abstract the composition is capable of reducing the irritation. Col. 1, lines 26-28, states that a “novel, topical skin lotion capable of stopping the itching and discomfort, calming the skin, ...” is provided. In col. 1, lines 36-30, it is set forth that the “lotion .... has soothing and calming qualities to decrease the irritation and ...”.

US 4,855,137 discloses a cosmetic composition having a skin calming and skin

regenerating effect (see title; col. 1, lines 8-10; col. 1, lines 32-34; col. 1, lines 43-44; col. 2, lines 5-9). Col. 2, lines 27-32, sets forth that after treatment with the composition “the skin was calmed and refreshed”. Note that claim 1 is directed to a “cosmetic composition having a skin-calming and skin-regenerating effect...”. There is no explicit explanation as to the skin-calming effect in this patent, i.e., the person skilled in the art knows “skin-calming”.

US 6,231,835 discloses (see Abstract) calming the itch caused by athlete’s foot, insect bite etc.

Bendova et al. “Protective Effects of Selected Active Ingredients of Cosmetic Products”; Posters in Exog. Dermatol. 2004, 3 191-200; page 194, sets forth that (2nd sentence) “Herbal ingredients are reported to .... and may offer a balanced complex of health effects as moisturizing, free radical scavenging, calming and....”.

EP 1 923 059 discloses in para 0018 that the claimed patch is effective in very irritated skin areas in that “ the refreshing action of the gel offers an immediate soothing and calming effect “.

As regards the term “normal skin” applicant submits several references to prove that the term is well understood in the art.

M. Mihm et al.; “The structure of normal skin and the morphology of atopic eczema”; The Journal of Investigative Dermatology,; 67; 305-312; 1976; refers to normal skin through the article as opposed to diseased skin. A section of normal skin is even illustrated on page 306.

US 6,566,136 discloses immortalized cell line derived from normal human skin tissue.

It is apparent from the attached literature that the term “calming” is a well established and widely used term in the art of dermatology. It is used in dermatology to refer to the effect of reducing itch or irritation of the skin or pain related to dry skin or psoriasis or insect bites or inflammatory skin conditions or allergic reactions etc. (skin reactions such as sunburn or itchy and irritated skin as a result of an insect bite are not skin diseases; the skin is still normal skin). Thus, calming (soothing) may refer to diseased skin as well as to normal skin. For example, in case of an insect bite the skin is not

diseased, it is simply irritated by an allergic reaction; likewise, dry skin is not diseased skin in the pathological sense; it is simply too dry because of exposure to sun, too much use of detergents, soaps etc. and may be itchy and scaly; therefore a calming or soothing effect is desirable for dry skin (normal - not diseased - skin) as it would be for treating diseased skin as in case of psoriasis, for example.

It is therefore respectfully submitted that a person skilled in the art will know and understand the term "calming" as well as the term "normal skin".

### **Rejection under 35 U.S.C. 103**

Claim 28 stands rejected under 35 U.S.C. 103(a) as being unpatentable over *US 5,741,513*.

The examiner argues that the cited reference discloses a method for reducing inflammation in diseased skin by administering a substance that comprises phosphatidyl choline (neutral phospholipid) and acidic phospholipid, wherein phosphatidyl choline is a zwitterion and comprises both a positive and a negative charge and is thus neutral. Thus, the invention as claimed is obvious.

Claim 13 which defines the phospholipid gel topically administered in the method of claim 28 has been amended to read "consisting of" so that now a gel is defined that consists of a first phospholipid, a second phospholipid, **water**, and optionally a pharmacologically active substance, wherein the first phospholipid is a neutral phospholipid and the second phospholipid is a negatively charged phospholipid.

The gel according to the present invention that is administered according to claim 28 is thus free of alcohol and contains only water in the gel; see page 2, lines 10 to 17.

The compositions of *US 5,741,513* contain alcohol. As set forth in col. 3, lines 27-32, the system is built up from liposomes consisting of a phospholipid concentrate of specific composition, alcohol and water in specific concentrations, wherein the aqueous phase is virtually exclusively the internal phase. Col. 4, lines 60-63, sets forth that the alcohol is employed in amounts of 14 to 20 parts by weight per parts by weight of the phospholipid composition. There is no suggestion or motivation in the entire reference to eliminate alcohol and use only water.

Therefore, claim 28, employing a gel containing exclusively water, is not obvious in view of *US 5,741,513*.

Reconsideration and withdrawal of the rejection of the claim under 35 USC 103 are respectfully requested.

### **CONCLUSION**

In view of the foregoing, it is submitted that this application is now in condition for allowance and such allowance is respectfully solicited.

Should the Examiner have any further objections or suggestions, the undersigned would appreciate a phone call or **e-mail** from the examiner to discuss appropriate amendments to place the application into condition for allowance.

Authorization is herewith given to charge any fees or any shortages in any fees required during prosecution of this application and not paid by other means to Patent and Trademark Office deposit account 50-1199.

Respectfully submitted on May 3, 2010,

/Gudrun E. Hockett/

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